

**King, Valerie A.**

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**From:** Charles Borg [cborg@watchpc-solutions.com]  
**Sent:** Monday, February 23, 2004 11:17 AM  
**To:** Valerie A. King  
**Cc:** Kimberly Prchal; A. Michelle Ramsay; Maria Gogova; Barbara K. Zedler; Paul. Mendes  
**Subject:** Approval for installing WatchPC Data Upload and Verification Software (MARL/02/03 Study)



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Dear Valerie:

Good to hear from you! I trust you're keeping well, too.

I hope Maria and the clinical group will get access soon to the MARL/02/03 WatchPC subject compliance program. As for your IT group's information:

1. Licenses: See attached documents. One is for the Electronic Patient Diary Software; the other is for the WatchPC Administration Program.

2. Software installation: For the MARL/02/03 study we provide an installation CD-ROM that allows PM personnel to view the data, in Richmond, from the study in Phoenix. The program version is "MDSPS-AA05796 (MARL/02/03) Data Upload and Verification Program Version 2.1". The CD-ROM includes the latest database of the study available at the time of issue (Feb 4/04).

3. Database updates: Every second week we will send you a database update that includes the results of the latest returns of subjects. This is an .mdb file that has been screened and reviewed by our database manager. This database update is e-mailed to you in form of a dated zip file, to a designated to a person/address designated by you, for updating the MARL/02/03 WPC files.

4. New studies: Installation of WatchPC Administration (patient compliance) software for other studies will need to follow the same process. You will receive a new installation CD-ROM for every new study that includes specific IDs for the study. These procedures are to keep you within the FDA Part 11 compliance guidelines of electronic data management.

I hope this answers your questions.

Best regards,

Charles

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-----Original Message-----

From: Valerie.A.King@pmusa.com [mailto:Valerie.A.King@pmusa.com]  
Sent: Friday, February 20, 2004 13:47  
To: cborg@watchpc-solutions.com  
Cc: Maria.Gogova@pmusa.com

Subject: WatchPC Data Upload and Verification Software (MARL/02/03  
Study) V 1.3

Dear Charles:  
I hope this finds you well.

In the context of determining whether we will be allowed to install the above referenced software on our computers, our IT group has requested documentation of the licensing relative to this software. Could you please provide me with that?

Also, am I correct in understanding that Maria would need both the data upload software 1.3 AND the WPC Installation software version 2.0 installed on her computer in order for her to read the files?

Lastly, could you please confirm whether for any subsequent studies that we would need to install this software (either or both) again as they might have been prepared for that specific study? That is my understanding, but that may be incorrect.

Please let me know as soon as possible.

Kind regards,  
Valerie